

PSJ10 Exh 62

A Watson Pharma, Inc.

Call Center Operations Call Center Operational Procedure

PROCEDURE:	Suspicious Orders of Controlled Drugs		
WRITTEN BY:	Judy Callahan	DATE:	May 3, 2004
Call Center Policy Number:	OPDCC 507509-03.00	Policy Effective Date	May 3, 2004
REVISION WRITTEN BY:		REVISION DATE:	
Supersede CC Policy #	CC 1007.00	CC Policy Date:	09/03
cSOP Reference #	cSOP 11-004	cSOP Ref. Date:	May 3, 2004

- I. **Purpose:** To assure distribution of controlled drugs is monitored for excessive use by an individual location using the DEA number as the identifier.
- II. **Scope:** This procedure applies to all controlled drugs distributed by Watson Laboratories, Inc. and its Subsidiaries.

DOCUMENT REFERENCES:

<u>Document Number</u>	<u>Document Title</u>
CTMAN-80-041-CC-OPR	Order Processing
CTMAN-80-041-CC-OPS	Order Processing Supervisor

ATTACHMENTS:

<u>Document Number</u>	<u>Document Title</u>
N/A	N/A

DEFINITIONS:

•	DEA	Drug Enforcement Agency
• A	SOMS	Suspicious Order Management System

III. Procedure:

1.0 Process for Suspicious Orders of controlled drugs

<u>Responsibility</u>	<u>Action</u>
General	1.1 The SAP system compiles a past history of controlled substance drug product orders by each customer to establish a normal order size and order frequency. This is accomplished through the normal Sales Order process see CTMAN-80-041-CC-OPR, Order Processing, for details on this process.
Call Center Management/ Controlled Substance Compliance Management	1.2 The SOMS Multiplier Table is determined by Call Center Management and the Controlled Substance Compliance Department.



A Watson Pharma, Inc.

Call Center Operations **Call Center Operational Procedure**

PROCEDURE:	Suspicious Orders of Controlled Drugs		
WRITTEN BY:	Judy Callahan	DATE:	May 3, 2004
Call Center Policy Number:	OPDCC 507506-03.00	Policy Effective Date	May 3, 2004

- | | | | |
|--|---|---|--|
| | 1.2.1 | See CTMAN 80-045-CC-LEM, License Entry and Management for description of system functionality with regards to the establishment of SOM levels, as well as how to access this information. | |
| Order Processing Representative License Administrator | 1.3 | The list is to be updated by written request to the customer approximately 30 days prior to the expiration date of the current registrations. | |
| | 1.4 | The license administrator will review the SOMS report, and then contact the customer to confirm the quantity ordered and verify the reason for a larger or more frequent order. | |
| | 1.5 | Once this SOMS report is confirmed and verified by the Customer, the SOMS report is signed and marked with a reason code by the license administrator and submitted to the Supervisor or Management for review and signature. | |
| | 1.6 | The license administrator will be responsible to ensure that pending sales orders on hold due to suspicious order (SOMS) violation are investigated. | |
| | 1.7 | The license administrator will release pending orders due to SOMS violations by canceling the order, or reducing the quantity, per customer requirements. | |
| | 1.8 | If the SOMS violation cannot be resolved by canceling the order or reducing the quantity, the license administrator will escalate the suspicious order to the next level. | |
| | 1.9 | Determine if the order does or does not classify as suspicious. | |
| | 1.10 | If a valid reason (based on objective criteria) does not exist, the order will be deemed as a suspicious order and will not be filled. Report suspicious issue to Control Substance Compliance Department. | |
| | Controlled Substance Compliance Department Order Processing Representative | 1.11 | The control Substance Compliance Department will determine the next level of Communication. |
| | | 1.12 | File a copy of the SOMS Report, along with the customer purchase order, in the suspicious order record file. |